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**Celerion Expands its Cell-Based Assays Capabilities in Global Bioanalytical Services.**

(Lincoln, NE; Nov 3, 2014) – [Celerion](#) announces the expansion of laboratory capabilities to meet growing demand for cell-based assays. Assays involving whole cells provide a variety of measures of drug activity or effect that can be important endpoints in clinical research. Celerion has expanded this capability in response to client demand for immunogenicity assessment for large molecule analysis and for immune monitoring assays in drug development. It also supports the recently issued FDA Guidance on [“Immunogenicity Assessment for Therapeutic Protein Products”](#).

For more than 30 years, [Celerion’s laboratory in Zurich, Switzerland](#) has supported immunogenicity testing to detect anti-drug antibodies in serum samples of animals or patients treated with new drug therapies under development. Through investments in state-of-the-art technology and resources, Celerion is able to support clients’ evolving needs in immunogenicity assessment, by leveraging appropriate biological models for the assessment of antidrug neutralizing antibodies. This methodology can be used to examine cell morphology, cell differentiation, cell cycle effects including apoptosis, protein regulation including modification and expression levels, and transcription activity. These assays are important biomarkers in clinical research programs of large molecule and biologically manufactured drugs including biosimilars.

Celerion’s laboratory in Lincoln, Nebraska is focused on flow cytometry, a powerful technique that allows the detection and measurement of different cell populations within a biological sample. The use of flow cytometry enables Celerion to develop de-novo flow cytometry assays such as cell signaling, target engagement, natural killer cell and immune function assessments. These methods are utilized to measure therapeutic response, stratification of patient populations and the evaluation of predictive diagnostic or prognostic biomarkers in clinical research. Many of these assays require fresh samples, so being co-located within Celerion’s clinical research unit in Lincoln, Nebraska enables clients to leverage this technology as part of early evaluation of a new drug’s safety and pharmacological effects.

“Utilizing cell-based assay capabilities enables our clients to gain key safety data that allows them to make critical decisions for their drug development programs,” said [Ray Farmen](#), Ph.D., Vice President of [Global Bioanalytical Services](#) at Celerion. “Celerion now offers a complete package of immunogenicity testing with the addition of neutralizing antibody assessments at our Zurich facility. Flow cytometry capabilities are most valuable when performed in immediate proximity to where clinical conduct is performed, making Celerion’s clinical facilities in Lincoln, Nebraska an ideal place to perform such research.”

Investing in cell-based assay technology is aligned to Celerion’s goal of providing robust and integrated ways for clients to evaluate the true potential of new drug candidates early in clinical development.



## **About Celerion**

Celerion, a leader in early clinical research, delivers Applied Translational Medicine. Celerion applies our expertise and experience to translating information gained in research discoveries, to knowledge of drug action and effect in humans to support early drug development decisions and the clinical pharmacology labeling of new medicines.

With over 40 years of experience and 750 global clinic beds (including 24 in-hospital), Celerion conducts and analyzes First-in-Human, clinical Proof-of-Concept, Cardiac Safety Services (TQT, robust QT), ADME and NDA-enabling clinical pharmacology studies. Celerion provides expertise on modeling and simulation, study design, medical writing (protocols and reports), clinical data sciences, biostatistics, and PK/PD analysis as well as small and large molecule bioanalytical assays through clinical drug development. Regulatory, drug development and program management complement Celerion's service offerings. For more information please visit [www.celerion.com](http://www.celerion.com).